§ 868.1750 Pressure plethysmograph.

(a) *Identification.* A pressure plethysmograph is a device used to determine a patient's airway resistance and lung volumes by measuring pressure changes while the patient is in an airtight box.

(b) *Classification.* Class II (performance standards).

§ 868.1760 Volume plethysmograph.

(a) *Identification.* A volume plethysmograph is an airtight box, in which a patient sits, that is used to determine the patient's lung volume changes.

(b) *Classification.* Class II (performance standards).

§ 868.1780 Inspiratory airway pressure meter.

(a) *Identification.* An inspiratory airway pressure meter is a device used to measure the amount of pressure produced in a patient's airway during maximal inspiration.

(b) *Classification.* Class II (performance standards).

§ 868.1800 Rhinoanemometer.

(a) *Identification.* A rhinoanemometer is a device used to quantify the amount of nasal congestion by measuring the airflow through, and differential pressure across, a patient's nasal passages.

(b) *Classification.* Class II (performance standards).

§ 868.1840 Diagnostic spirometer.

(a) *Identification.* A diagnostic spirometer is a device used in pulmonary function testing to measure the volume of gas moving in or out of a patient's lungs.

(b) *Classification.* Class II (performance standards).

§ 868.1850 Monitoring spirometer.

(a) *Identification.* A monitoring spirometer is a device used to measure continuously a patient's tidal volume (volume of gas inhaled by the patient during each respiration cycle) or minute volume (the tidal volume multiplied by the rate of respiration for 1 minute) for the evaluation of the patient's ventilatory status.

(b) *Classification.* Class II (performance standards).

§ 868.1860 Peak-flow meter for spirometry.

(a) *Identification.* A peak-flow meter for spirometry is a device used to measure a patient's maximum ventilatory flow rate.

(b) *Classification.* Class II (performance standards).

§ 868.1870 Gas volume calibrator.

(a) *Identification.* A gas volume calibrator is a device that is intended for medical purposes and that is used to calibrate the output of gas volume measurement instruments by delivering a known gas volume.

(b) *Classification.* Class I (general controls). The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter subject to the limitations in § 868.9.

[47 FR 31142, July 16, 1982, as amended at 61 FR 1119, Jan. 16, 1996; 66 FR 38793, July 25, 2001]

§ 868.1880 Pulmonary-function data calculator.

(a) *Identification.* A pulmonary-function data calculator is a device used to calculate pulmonary-function values based on actual physical data obtained during pulmonary-function testing.

(b) *Classification.* Class II (performance standards).

§ 868.1890 Predictive pulmonary-function value calculator.

(a) *Identification.* A predictive pulmonary-function value calculator is a device used to calculate normal pulmonary-function values based on empirical equations.

(b) *Classification.* Class II (performance standards).

§ 868.1900 Diagnostic pulmonary-function interpretation calculator.

(a) *Identification.* A diagnostic pulmonary-function interpretation calculator is a device that interprets pulmonary study data to determine clinical significance of pulmonary-function values.

(b) *Classification.* Class II (performance standards).